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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/056,019	04/07/1998	ELAINE I. TUOMANEN	44158/207989(5853-2)	4774

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EXAMINER

ALLEN, MARIANNE P

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/06/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/056,019

Applicant(s)

TUOMANEN ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/2/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 46-72, 74-78, 80-83 and 87-98 is/are pending in the application.
- 4a) Of the above claim(s) 53, 64, 80, 90, 95 and 96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46, 50-52, 54-63, 65-72, 74-78, 81-83, 87-89, 91-94, 97 and 98 is/are rejected.
- 7) ☒ Claim(s) 47-49 is/are objected to.
- 8) ☒ Claim(s) 46-72, 74-78, 80-83 and 87-98 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 33.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 73, 79, and 84-86 have been cancelled and claims 95-98 have been newly introduced.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Claims 53, 64, 80, and 90 remain directed to an invention that is independent or distinct from the invention originally claimed. Newly submitted claims 95-96 are also directed to an invention that is independent or distinct from the invention originally claimed for the same reasons: Polypeptide vaccine claims properly correspond to group V, claims 42-43, in the original restriction requirement (Paper No. 10). This invention was not elected.

Claims 64, 90, and new claim 95 are directed to a polypeptide “immunogenic against bacterial infection.” While the claims do not use the term “vaccine” this appears to be the intent of the claim. Compositions of this nature are classified in class 424, subclass 184.1, for example. Should applicant disagree with the interpretation of the claim, they are invited to explain how the claimed invention differs from a vaccine.

Claims 53, 80, and new claim 96 are directed to a pharmaceutical composition. The use of the term “pharmaceutical” in the preamble and the absence of a particular intended use in the body of the claim requires that all intended uses be enabled. Applicant is reminded that the full breadth of the claim must be enabled. In the absence of a particular intended use all reasonable intended uses must be enabled. As such, these claims are considered to encompass polypeptide vaccines. Compositions of this nature are classified in class 424, subclass 184.1, for example.

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Should applicant disagree with the interpretation of the claim, they are invited to explain why the claimed invention does not encompass vaccines.

It is noted that applicant has cancelled claim 73 explicitly directed to vaccines.

The specification does not appear to provide a specific definition of what was intended to be encompassed by the recitation “immunogenic.” The broadest reasonable interpretation of “immunogenic” includes the ability to raise an antibody against the recited polypeptide. As such, claims reciting “polypeptide is immunogenic” are not considered to be directed to vaccines.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53, 64, 80, 90, and 95-96 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 53, 64, 80, 90, and 95-96 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Specification***

The abstract submitted is noted.

The new CRF and paper copy of the sequence listing as well as the amendment to the description of Figure 2A are noted.

***Claim Rejections - 35 USC § 112***

Claims 51, 57-63, 65-68, 71-72, 79, 84-89, and 91-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 51 and 57 recite “up to 475 amino acids.” These claims continue to contain new matter for reasons of record. The specification discloses particular proteins of 475 amino acids having the subsequence in the recited SEQ ID NO. Applicant appears to believe that the claim encompasses fragments of these disclosed proteins that include the named subsequence in the recited SEQ ID NO. First of all, this subgenus is not contemplated by the specification. Secondly, the claims are not limited to this concept. They embrace any protein of the recited size (i.e. up to 475 amino acids) having the recited sequence (i.e. SEQ ID NO: 5) embedded in it. A fair reading of the specification does not contemplate this invention.

Claims 52 and 58 recite “up to 460 amino acids.” These claims continue to contain new matter for the reasons of record and as discussed above.

Claim 59 has been newly amended to recite “at least 138 consecutive amino acids of SEQ ID NO: 24.” Basis is stated to be in Figure 2A-1 which shows a particular 138 amino acid fragment of SEQ ID NO: 24. This claim is considered to contain new matter. This particular fragment is not being claimed and there is no general concept disclosed for all polypeptides having the functional property and size limitations set forth in the claim.

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Claim 60 has been newly amended to recite “up to 398 amino acids.” Basis appears to be in Figure 2B. This claim is considered to contain new matter. This particular fragment is not being claimed and there is no general concept disclosed for all polypeptides having the functional property and size limitations set forth in the claim.

Claims 67, 69 (parts c-e), 70 (parts c-e), 71 (parts a-e), 72 (parts c-e), 74, 75, 81, 87, and 93 are likewise considered to contain new matter with respect to the amendments with respect to size.

In addition claim 60 still recites “at least one to 57 amino acid substitutions” and continues to contain new matter for reasons of record. The claim embraces any amino acid substitution at one to 57 unspecified positions. The specification disclosed particular substitutions at particular positions. The generic concept presently claimed by applicant is not disclosed. See also claims 61-63, 67-68, 87-89, and 93-94 and dependent claims.

Claims 65 and 91 recite “host preferred amino acid substitutions.” These claims continue to contain new matter for reasons of record. Only codons preferred for expression in selected non-mammalian hosts are contemplated on page 13. Pages 32-33 disclose selecting vectors, host cells, and expression control sequences. Preferred codons for hosts generally are not disclosed nor contemplated on these pages.

Claims 71-72 recite “retains native tertiary structure” with respect to all of the named SEQ ID NOS. These claims continue to contain new matter for reasons of record. Applicant is requested to point to the portion of the disclosure that describes what the native tertiary structure of full length choline binding protein A is and how one would recognize this property or

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structure for all of the named SEQ ID NOS. and polypeptides encompassed by the claims. No three dimensional structure is disclosed in the specification.

Claims 69-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record.

Claims 55 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 remains confusing in reciting “comprising SEQ ID NO: 22” and being dependent upon claim 54 which comprises “SEQ ID NO: 4.” SEQ ID NO: 22 does not encompass SEQ ID NO: 4. Applicant appears to be arguing that the claimed polypeptide contains both sequences in a larger polypeptide. The claim does not say this and as such is confusing. Note that it is unclear if SEQ ID NO: 22 is fused to SEQ ID NO: 4 in the naturally occurring order or some other configuration. Applicant is inviting a new matter rejection.

Claim 82 remains confusing in reciting “comprising SEQ ID NO:23” and being dependent upon claim 81 which comprises “SEQ ID NO: 10” for reasons of record and in view of the remarks with respect to claim 55.

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Claims 46, 50-52, 54-63, 65-72, 74-78, 81-83, 87-89, 91-94, and 97-98 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: inclusion of entirety of sequence responsible for lectin activity.

This rejection is maintained for reasons of record. Applicant has admitted that the claims do not recite the structural characteristics required to achieve the functional activity. As such, the claims do not clearly set forth the polypeptides embraced by the claims. The claims deliberately obscure the structure of the polypeptides being claimed.

### ***Conclusion***

Claims 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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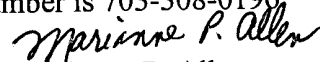
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa

March 5, 2003